

## Remarks

Claims 5-8, 12-15, 17-20, 23-25, 29, 31, 35-37, 44-48, 62-67, 75-85, 87, 89-97, 99, 101-103, 108, 109, 111, 112 and 116 are pending in this application. Claims 62 and 66 have been amended in various particulars as indicated hereinabove.

The abstract of the disclosure was objected to. A copy of the Abstract on a separate page, responsive to the objection, has been enclosed with this response.

Claim 91 was rejected under 35 U.S.C. 112, second paragraph. It is believed that Claim 91 as rewritten is in compliance with 35 U.S.C. 112, second paragraph.

Claims 62-67, 92-94 and 96 were rejected under 35 U.S.C. 102(b) over Wolbarsht et al. (US 5,267,856). This rejection is respectfully traversed for the following reasons.

It is well established that a claim is anticipated under 35 U.S.C. § 102, only if each and every element of the claim is found in a single prior art reference<sup>1</sup>. Moreover, to anticipate a claim under 35 U.S.C. § 102, a single source must contain each and every element of the claim “arranged as in the claim.”<sup>2</sup> Missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference<sup>3</sup>. If each and every element of a claim is not found in a single reference, there can be no anticipation.

The Patent Office wrote that:

“Wolbarsht shows a method of hard tissue modification comprising selectively heating a porous layer of hard tissue (tooth enamel) to cause a porous layers to fuse (col. 1, lines 30-35) and have a composition differing from that of the hard tissue originally (crystals have been fused).”

Col. 1, lines 30-35 of Wolbarsht say the following:

“A YAG laser has also been used to remove incipient carious lesions and/or stain from teeth (U.S. Pat. No. 4,521,194). This use of a YAG laser was found to

<sup>1</sup> Veregal Bros. v Union Oil Co. of California, 814 F.2d 628, 631, 2USPQ2d 1051, 1053 (Fed. Cir. 1987).

<sup>2</sup> Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 716, 223 U.S.P.Q. 1264, 1271 (Fed. Cir. 1984). Lewmar Marine Inc. v. Barient, Inc., 827 F.2d 744, 747, 3 U.S.P.Q. 2d 1766, 1768 (Fed. Cir. 1987), cert. denied, 484 U.S. 1007 (1988).

<sup>3</sup> Titanium Metals Corp. v. Banner, 778 F.2d 775, 780, 227 U.S.P.Q. 773, 777 (Fed. Cir. 1985).

slightly fuse the crystals which form the tooth enamel and make the tooth enamel more impervious to decay.”

There is nothing in the cited excerpt that says anything about selective heating, and there is nothing in that excerpt that says anything about selectively heating a porous layer. YAG laser is these used only for the removal, but not for the modification of an incipient carious lesion.

Specifically, the YAG laser referenced in Wolbarsht is not even capable of selectively heating a layer, because the YAG laser penetrates deeply into the bulk of the irradiated material, which is different from just selectively heating a layer. A coefficient of absorption of enamel for a YAG laser is lower than  $0.1 \text{ cm}^{-1}$  which means that it penetrates through the entire enamel layer into the dentine, thus being incapable of selectively heating a surface layer.

There is also no porous layer disclosed in the cited excerpt of Wolbarsht. The slight fusion of the crystals of the tooth enamel means that the microcrystals from enamel prisms with typical size  $(14-26) \text{ nm} \times (27-78) \text{ nm}$ , which are naturally slightly misaligned and naturally have some intercrystalline space between them, can get slightly fused to one another. What is described in that excerpt of Wolbarsht is a typical polycrystalline structure with some tiny intercrystalline spaces between crystals. Those crystals are not in a layer of hard tissue and they don't have pores.

Moreover, the Wolbarsht patent does not provide any disclosure at all regarding formation of the porous layer, as claimed in amended Claim 62. All that Wolbarsht could possibly refer to is a polycrystalline structure of the enamel which simply exists in the enamel as its structure without being formed by anyone. The Patent Office refers to Col. 3, lines 49-65 of Wolbarsht. Applicants assert that what is described in that excerpt is a description of naturally occurring defects in the bone, teeth, enamel dentin, ceramics. Nothing in that description suggests that the pores are formed as a step, or that those pores were formed in a layer, as claimed in Claim 62, and not in the bulk hard tissue material. Therefore, no “forming the porous layers of the hard tissue” step could be found in Wolbarsht. Wolbarsht teaches use of water to penetrate into these defects for ablation

of hard tissue and teaches away from modification of a porous layer. There is no disclosure in that excerpt that the porous layer is selectively heated, Wolbarsht merely states that some crystals in the bulk material slightly fuse. If indeed the crystals in the bulk enamel tooth material in Wolbarsht would be heated up to its melting temperature, that heat would badly burn the patient's gum. It is the selective heating only of that porous layer in the referenced Claim that allows the temperature to reach the melting temperature without burning the rest of the tooth and the surrounding gum.

With regard to Claim 64, Applicants assert that Wolbarsht contains no disclosure of selectively heating a porous layer of the hard tissue, the layers having the thickness ranging between 0.5 and 100 microns. No numeric ranges of any porous layer of the hard tissue could be found in Wolbarsht.

With regard to Claim 65, Applicants assert that there is no disclosure in Wolbarsht where heating the porous layers to a temperature higher than the melting temperature of the hard tissue is disclosed. Col. 1, lines 30-35 of Wolbarsht states that crystals slightly fuse.

Also contrary to what is claimed in the referenced Claim 65, the disclosure in Col. 5, lines 22-68 of Wolbarsht pertains to the process of laser surgery by laser ablation (referencing enamel and dentin ablation, for example). It has nothing to do with heating a porous layer up to the melting temperature of the hard tissue, as claimed in Claim 65.

With regard to the statement of the Patent Office that Wolbarsht discloses "a composition differing from that of the hard tissue originally", because crystals have been fuse (citing col. 1, lines 30-35) – it is incorrect. Fusing or melting a material does not change its composition. Heating or cooling a substance can change its aggregate state (liquid to vapor, liquid to solid, for example), but the composition of matter remains the same, unless a different component is added (or removed) from the original substance. Therefore, Claim 94 is not anticipated by Wolbarsht, since Claim 94 recites a post-treatment layer having a composition differing from that of the hard tissue.

The Office Action also states that “[T]he layer is impregnated with particles before heating (col. 3, lines 49-65)”. Applicants respectfully disagree. That excerpt of Wolbarsht describes the spaces between naturally occurring defects in the bulk tooth material filled with water as an absorbing liquid for initiating the ablation process. Contrary to that description in Wolbarsht, Claim 96 of the present application recites particles, not water as an absorbing liquid.

Therefore, for the above-articulated reasons Claims 62-67 as amended, 92-94 and 96 are in compliance with the requirements of 35 U.S.C. 102(b) over Wolbarsht. Applicants request that the present rejection be withdrawn and that the referenced Claims be moved to allowance.

Claims 62, 75-77, 79-83, 87, 89-90 and 94 were rejected under 35 U.S.C. 102(b) over Levy (US 5,194,005). This rejection is respectfully traversed for the following reasons.

The Patent Office stated that “Levy shows a method of hard tissue modification comprising impregnating a porous layer of hard tissue such as a carious lesion, open dentine, cementum, bone or cartilage (col. 1, lines 16-39) particles (hydroxyapatite solution)...”. Contrary to that statement, there is nothing in that portion of the Levy disclosure that either talks about a porous layer, or about selectively heating a porous layer, or about impregnating the porous layer with particles. For example, the whole Levy patent has to do with drilling a tooth and filling a cavity with a filling material. A cavity is not a porous layer, and drilling a cavity of not forming a porous layer or selectively heating it. Moreover, a filling material in Levy is not particles. Col. 2, lines 44-57, cited by the Patent Office, describes that:

a filling material for teeth is constituted by a mixture formed from a liquid component composed of phosphoric acid and water and a powder component composed of a ceramic and hydroxyapatite, with the ingredients mixed in a proportion to form a paste having a consistency such that the paste is workable and sufficiently self-supporting to be applied to the opening with a spatula and remain in place (emphasis added).

The Levy patent describes curing of the filling material with IR, Nd:YAG laser, similar to the curing method by the blue or UV light, which method has nothing to do with the hard tissue surface modification, as claimed in the referenced claims. The above-presented excerpt from Levy makes it clear that the filling material is a paste, not in the form of particles, as claimed in independent Claims 62, 75, 80, 89, 94 are not anticipated by Levy and should be allowable.

Moreover, the Office Action stated that col. 2, lines 44-57 of Levy refer to the particles “having a fluidity temperature about the same /higher as the melting temperature of the hard tissue of the porous layer”. Applicants’ attorney has carefully reviewed the referenced portion of the Levy disclosure, but was unable to find any word there pertinent to a fluidity temperature, heating or even particles characterized by any temperature. A simple Edit-Find search of the text of the Levy patent brings zero words with the roots “melt” or “fluidi”. Therefore, that portion of the Levy patent cannot disclose what the Patent Office stated.

Col. 3, lines 18-25 of the Levy patent, cited by the Patent Office, says the following:

The application of radiation to the filling material will promote the growth of a crystal structure in that material and create a strong bond between the hydroxyapatite and the surrounding tooth material. The radiation will be applied until a crystal structure appears, this generally requiring application of the radiation for a period of 10-30 seconds.

The Office Action, referring to that excerpt, stated that it discloses “selectively heating the porous layer to a temperature higher than the melting temperature of the hard tissue, causing the hard tissue and the particles to fuse”. Applicants assert that the Levy patent as a whole, and the cited excerpt in particular, say nothing about selective heating of the porous layers or melting the particles. Levy refers to general heating for slow crystal growth, which is completely different from selectively heating a layer up to at least the melting temperature of the particles. The Levy patent actually teaches away from selectively heating of the layer of the hard tissue, because the Levy disclosure requires crystallization of all bulk (volume) of the filling material in the cavity, as well as a strong

bonding of filling material with surrounding tooth material. As described in that patent, Levy's process of crystallization and bonding requires 10 -30 sec. It is impossible to perform any fusion of a porous layer of hard tissue or melting of the hard tissue. The temperature of such Levy process will be above several hundred degrees, meaning that maintaining such a temperature in the living tooth for 10 -30 sec will completely burn and damage the pulp and the surrounding gingival tissue. Therefore, Applicants assert that Claims 62, 75-77, 79-83, 87, 89-90 and 84 are in compliance with the requirements of 35 U.S.C. 102(b) over Levy. Applicants request that the present rejection be withdrawn and that the referenced Claims be moved to allowance. Claims 76-77 depend off independent Claim 75, Claims 82-83 depend off independent Claim 80 and should be allowable.

With regard to Claims 79 and 81, the Office Action stated that "selective heating comprises heating by acoustic energy, electromagnetic energy, light energy microwave energy, radio frequency electric current or combination thereof (col. 3, lines 6-25)". Contrary to that statement, the Levy disclosure only refers to laser energy, and nothing else. The Patent Office is respectfully asked to specifically refer to the portion of Levy where a description of any other energy used for the Levy curing process is mentioned. Therefore, Claims 79 and 81 are patentable over the Levy patent and should be allowed.

With regard to Claims 87 and 89, the Patent Office wrote that "the filler material is fluidified before being impregnated into the porous layers (hydroxyapatite solution; col. 2, lines 44-57)." Contrary to that assertion, Claims 87 and 89 recite a fluidified material preheated at least about its fluidity temperature. To heat a material above its fluidity temperature means to heat it at least up to its melting temperature. There is nothing like that disclosed in the cited Levy excerpt, which only describes a mixture of water, phosphoric acid and a powder component. Therefore, Claims 87 and 89 are patentable over the Levy patent and should be allowed.

Claims 78 and 84-85 were rejected under 35 U.S.C. 103(a) over Levy. Claims 91 and 95 were rejected under 35 U.S.C. 103(a) over Levy in view of Auge, II (US

2002/0022846). Claims 92-93 were rejected under 35 U.S.C. 103(a) over Levy in view of Wolbarsht. These rejections are respectfully traversed for the following reasons.

For an obviousness rejection to be proper, the Patent Office must meet the burden of establishing a prima facie case of obviousness. The Patent Office must meet the burden of establishing that all elements of the invention are disclosed in the cited publications, which must have a suggestion, teaching or motivation for one of ordinary skill in the art to modify a reference or combined references<sup>4</sup>. The cited publications should explicitly provide a reasonable expectation of success, determined from the position of one of ordinary skill in the art at the time the invention was made<sup>5</sup>.

For the reasons and arguments articulated above, a combination of publications cited by the Patent Office in its 103(a) rejection does not disclose, suggest, teach or even hints to each and every element as disclosed in the pending base independent Claims 62, 75, 80, 94. Therefore, their respective dependent Claims 78, 84-85, 91, 95, 92-93 cannot be obvious in view of the cited publication and are in compliance with the requirements of 35 U.S.C. 103(a). Allowance of the referenced Claims is respectfully solicited.

It is believed that the present application is in condition for allowance. A Notice of Allowance is respectfully solicited. Should any questions arise, the Examiner is encouraged to contact the undersigned.

Respectfully submitted,

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<sup>4</sup> *In re Sang Su Lee*, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002).

<sup>5</sup> *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988); *In re Wilson*, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970).